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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,261	07/30/2003	Syed F. A. Hossainy	50623.276	8699
7590	07/24/2006			EXAMINER KENNEDY, SHARON E
Cameron Kerrigan Squire, Sanders & Dempsey L.L.P. Suite 300 One Maritime Plaza San Francisco, CA 94111			ART UNIT 1615	PAPER NUMBER

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/630,261	HOSSAINY ET AL.	
	Examiner Sharon E. Kennedy	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 March 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-6,8-17 and 19-23 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-6,8-17 and 19-23 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

## DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

### ***Claim Rejections - 35 USC § 112***

Claims 1-6, 8-16, 18-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1 and 12, it is unclear what is meant by “biological moiety that produces a biological response.” Clearly applicant is entitled to characterize the “biocompatible block” as a biological moiety since applicant is entitled to be their own lexicographer, however, modifying the “biological moiety” by requiring that it produce a “biological response” raises uncertainty. First, “biological response” is not defined in the specification. Secondly, these polymers are merely characterized as “biocompatible moieties” in the published application, [0040] of 2005/0025799 A1. Simply because a block polymer component is biocompatible does not mean that it produces a biological response. A biological response implies that there is a drug delivery, enzyme, etc., for example, however, this feature is not required until claim 9, which requires a biologically active agent. This further complicates the meaning because it is unclear if applicant is implying that the active agent is conjugated to the biological moiety. Accordingly, the claims are unclear. Applicant could correct the claims by deleting the requirement that

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the biological moiety produce a biological response, or characterize the block as described in the specification, merely that it is biocompatible.

Further regarding claim 23, to make this claim properly dependent upon claim 1, applicant must state that the coating further comprises phosphoryl choline or polyaspirin. Note is made of applicant's disclosure in published paragraph [0048] and the restriction applied by the European Patent Office (See "NPL Documents" dated 07/11/2005, page 6).

### ***Claim Rejections - 35 USC § 102***

Claims 1, 3-6, 8, 12, 14-17, 19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sakkers et al., "Assessment of bioactivity for orthopedic coatings in a gap-healing model" with reference to "PolyActive™" factsheet. Sakkers discloses on page 266 of the reference, under the heading "Implant materials", that implants were coated with "Polyactive™ 30-70. The fact sheet discloses that PolyActive™ is a multiblock copolymer based on PEG, poly(ethylene glycol) and PBT, poly(butlenes terephthalate). Accordingly, this anticipates the claimed poly(ethylene-glycol)-block-poly(butlenes terephthalate) of claims 8 and 19.

Note that multiple references may be used in a rejection under 35 U.S.C. 102. See MPEP 2131.01, entitled, "Multiple Reference 35 U.S.C. 102 Rejections." The secondary reference is being used to explain the meaning of PolyActive™ as used in the first reference. Note is also made of applicant's disclosure of PolyActive™ in paragraph [0045] in the published application.

Claims 1-5, 9, 12-16, 20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Loomis, US 6,005,020. Note the block copolymer formula in column 4, lines 3-34. The "A" polymers are disclosed in column 5, lines 26-39, the "B" polymers are disclosed in column 5, lines 47-57. Note the disclosure of poly(ester-amides) at column 5, line 30; polylactic acid at column 5, line 37; poly(ethylene) oxide at column 5, line 55. See claim 7 which discloses the polymer used as a coating on a stent. See also column 7, lines 50+. Regarding claims 9 and 20, see column 6, lines 53+.

Claims 1-6, 8-10, 12-17, 19-22 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Helmus et al., US 6,730,313. See especially column 19, lines 6-20, disclosing the block copolymer hydrogel coating comprising a hydrolytically labile extension such as polylactic acid, while the water soluble block may comprise poly(ethylene glycol). Note that the block copolymer preferably comprises a "water soluble central block segment sandwiched between two hydrolytically labile extensions." See column 19, lines 12-13. This anticipates the claimed poly(lactic acid)-block-poly(ethylene-glycol)-block-poly(lactic acid) block copolymer of claim 8 and 19. These coatings may be applied to stents (column 6, line 40). See also column 6, lines 45-47. Regarding claim 10, see column 8, lines 55+ regarding covalent attachment of bioactive materials.

Claims 1 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Hossiany et al., US 2004/0253203. See the entire document.

The applied reference has a common inventor(s) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art

under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

#### ***Allowable Subject Matter***

Claims 11 and 22 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: Regarding claims 11 and 22, the closest prior art is the patent to Michal et al., US 7,070,798, which discloses conjugated diazenium diolate (column 2, lines 19-21) which may be used as a coating for stents (column 5, line 6), however, there is no disclosure or suggestion of the claimed block copolymers.

#### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sharon E. Kennedy  
Primary Examiner  
Art Unit 1615